UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* ADAM HART,

Plaintiff-Relator,

v.

MCKESSON CORP., *et al.*,

Defendants.

No. 15-Civ-0903 (RA) (JLC)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

COVINGTON & BURLING LLP

Ethan M. Posner
Krysten Rosen Moller
Nicholas O. Pastan
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001
eposner@cov.com
krosenmoller@cov.com
npastan@cov.com

Thomas E. Garten
COVINGTON & BURLING LLP
3000 El Camino Real
5 Palo Alto Square
Palo Alto, CA 94306
tgarten@cov.com

Counsel for Defendants

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INTRODUCTION

Plaintiff-Relator Adam Hart's ("Relator") Second Amended Complaint ("SAC") fails to sufficiently state a claim against Defendants McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (collectively "McKesson") and fails to meet the particularity requirements of Federal Rule of Civil Procedure 9(b). Relator filed his original Complaint in this case more than seven years ago. The Government investigated Relator's allegations and declined to intervene. Relator amended his Complaint, and that First Amended Complaint ("FAC") was dismissed by this Court. Relator's third bite at the apple—filed with the benefit of significant discovery conducted while McKesson's Motion to Dismiss the FAC was pending—similarly fails. Even with the benefit of a year of discovery and the Court's clear guidance on how to plead scienter in a False Claims Act ("FCA") case premised on alleged violations of the Anti-Kickback Statute ("AKS"), Relator cannot cure the fundamental deficiencies in his complaint that this Court identified.

In the SAC, Relator relies on three types of new allegations, all of which fall far short of plausibly alleging that "McKesson knew its conduct was unlawful." *See* ECF No. 155 at 28–29. First, apparently just now remembering self-serving events that were omitted from his prior two complaints, Relator relies on three alleged nearly decade-old conversations with McKesson sales employees, which purportedly demonstrate that McKesson knew its conduct was "unethical" and "inappropriate." None of these new allegations shed any light on whether *McKesson* knew its conduct was *unlawful*. Second, Relator asks the Court to make a patently unreasonable inferential leap from a misleading snippet of a document produced in discovery. He asks this Court to assume that McKesson knew its provision of the Margin Analyzer ("MA") and Regimen Profiler ("RP") to its Open Market customers was unlawful because an executive forwarded lengthy reports related to a separate business division, which included minimal

references to the tools, with the brief, vague statement "You didn't get this from me . . . [.]" Third, Relator repeats unsupported allegations about McKesson's conduct after the relevant time-period that *the Magistrate Judge presiding over discovery in this case already rejected*. Other than these new categories of allegations, Relator relies on conclusory statements, tries to walk back allegations that the Court found undermine an allegation of scienter, and repeats claims already rejected by the Court as insufficient to allege scienter. Because the SAC contains no plausible allegations of scienter from which the Court can reasonably infer that McKesson knew its conduct was unlawful, it should be dismissed in full.

This Court should also dismiss Relator's allegations of a "nationwide" scheme for failing to meet the particularity requirements of Federal Rule of Civil Procedure 9(b). Instead of providing allegations describing specific nationwide conduct by McKesson employees, Relator's new allegations merely string together cherry-picked phrases from emails and other discovery documents followed by unsupported conclusory statements. These allegations only highlight that, with the benefit of over a year of discovery and years of investigation by the Department of Justice, Relator still cannot meet Rule 9(b)'s pleading standard for his nationwide claims.

STATEMENT OF THE CASE

I. Relator's Allegations and Procedural History

Relator initiated this qui tam action on February 6, 2015, by filing claims on behalf of the United States and twenty-nine states and the District of Columbia under the False Claims Act, 31 U.S.C. § 3729 et seq., and state false claims statutes. Relator alleges that McKesson violated the AKS and FCA by making available to their Open Market customers two "business management tools": the Margin Analyzer ("MA") and Regimen Profiler ("RP"). Second Amended Complaint ("SAC"), ECF No. 160 ¶ 51 The MA and RP are simple spreadsheet and web-based calculation tools containing information on a customer's purchases from McKesson and publicly available

information about the amount Medicare reimburses for specific drugs. SAC ¶¶ 5–7. Relator alleges that McKesson provided these tools on a quarterly basis to customers to "induce [them] to commit to purchasing specialty drugs from McKesson." *Id.* ¶¶ 4–5, 74–75. According to Relator, this resulted in the customers submitting false claims for reimbursement for the drugs they purchased from McKesson in lieu of purchasing the drugs from another distributor, in the quarter after McKesson offered or the customer received the tools. *Id.* ¶¶ 3, 57.

Over a period of several years, the United States investigated these claims and declined to intervene. The states and D.C. have also declined to pursue this case. The Court ordered the Complaint unsealed on May 29, 2020, ECF No. 15, and Relator filed his FAC on June 3, 2020, which was unsealed on July 10. ECF No. 24. The Court ordered discovery to proceed while McKesson's Motion to Dismiss Relator's FAC was pending. Substantial discovery proceeded over the course of more than one year, before a stay of discovery was granted. ECF No. 76.

II. The Court's Prior Ruling Dismissing the First Amended Complaint.

The Court dismissed Relator's FAC on May 5, 2022, holding that the FAC lacked allegations sufficient to meet the AKS' scienter requirement. ECF No. 155. Specifically, the Court found that the FAC failed to state a claim because it contained only conclusory allegations that McKesson acted with knowledge that its conduct was unlawful, *id.* at 28–29, and that because Relator failed to allege "facts from which the Court can infer Defendants knew the conduct was unlawful and proceeded with the business practice regardless," the FAC did not plausibly allege scienter under the AKS, *id.* at 30.

The Court also found that despite Relator's allegations that McKesson engaged in fraudulent conduct nationwide, the FAC did not identify "any particular oncology practices outside of Florida, Georgia, or Alabama[.]" *Id.* at 8. The Court did not, however, evaluate the sufficiency of Relator's allegations of a "nationwide scheme" involving MA and RP because

Relator represented that he would add additional nationwide allegations in an amended complaint. *Id.* at 33–34. The Court granted leave to amend. *Id.* at 35.

III. Relator's SAC Does Not Cure the Deficiencies Identified by the Court.

In response to the Court's order dismissing the FAC, Relator has added two new sections of allegations in the SAC that attempt to address the Court's finding that the FAC failed to plausibly allege scienter. Relator's new allegations of scienter in these sections and throughout the SAC fall well short of the standard adopted by this Court, which requires Relator to put forth plausible non-conclusory allegations that McKesson knew the complained-of course of conduct was unlawful, and often repeat allegations the Court already deemed insufficient to state a claim.

First, Relator adds a new section to the SAC titled "Additional Allegations of Scienter." This section contains (1) conclusory allegations that McKesson acted "knowingly and willfully" when offering the MA and RP as "unlawful kickbacks," SAC ¶¶ 156, 162; (2) allegations like those previously rejected by this Court as insufficient to allege scienter, such as the conclusory allegation that McKesson knew the MA and RP had value, *id.* ¶¶ 159, 162, and the general allegation that McKesson employees were aware of the AKS due to annual trainings, *id.* ¶¶ 157–59; and (3) allegations about previously undisclosed instant-message and in-person conversations between Relator and other McKesson employees that purportedly indicate McKesson's unlawful intent, *id.* ¶¶ 164–66. Some of these additional allegations are also incorporated into other sections of the SAC. *See, e.g.*, *infra* Section I.C. None of these allegations state a plausible claim for relief because the Court cannot reasonably infer from them that McKesson knew its conduct was *unlawful*. *See* ECF No. 155 at 12.

Relator attempts to support his new, conclusory allegations of scienter with references to McKesson documents produced in discovery. *See, e.g.*, SAC ¶ 160. A review of such

documents, which Relator selectively quotes but does not attach, demonstrates that he is asking the Court to make baseless, unreasonable inferences that cannot plausibly state a claim for relief.

Second, Relator adds a section titled "McKesson Has Destroyed Documents Evidencing Its Conduct," in which he attempts to impute scienter to McKesson by making outlandish and baseless allegations that McKesson purposefully destroyed evidence relevant to this lawsuit. SAC § VII(G). Specifically, Relator alleges that McKesson improperly destroyed documents, including Relator's laptop, records of compliance trainings, and documents about McKesson's use of the MA and RP from the relevant time period. SAC ¶¶ 168–70. Of course, these improper destruction allegations are false. And, Relator lacks a reasonable basis to make them—these same allegations were previously raised by Relator as part of a discovery dispute and Magistrate Judge Cott, who presides over discovery, rejected them after motions practice and a full hearing.[1] *See* ECF Nos. 133, 138; ECF No. 136, Hr'g Tr. (Dec. 2, 2021), at 18:18–19:10; ECF No. 144, Hr'g Tr. (Jan. 12, 2022), at 21:17–22:20. Relator cannot repurpose baseless allegations about document destruction that were already rejected to plausibly allege scienter.

Relator also appears to try to sidestep allegations he made in the FAC that McKesson publicized the use of the MA and RP, which the Court found undermined Relator's allegations of scienter. ECF No. 155 at 30. Relator now alleges that McKesson has "purged practically all mentions of the Margin Analyzer from its website[.]" SAC ¶ 167. This new allegation cannot save Relator's SAC, which in the very same paragraph makes clear that during the relevant time period McKesson "touted the Margin Analyzer on its website[.]" *Id.*

[1] This Court may take judicial notice of the prior court proceedings, including court transcripts and exhibits from related proceedings. *See Pelosi v. Spata*, 607 F. Supp. 2d 366, 371 (E.D.N.Y. 2009). Taking judicial notice of prior court proceedings is "properly considered on a motion to dismiss and do[es] not require the court to consider the motion as one for summary judgment." *Jackson v. New York*, 523 F. App'x 67, 68 (2d Cir. 2013).

Finally, in an attempt to bolster his unsupported claim that McKesson engaged in a "nationwide" fraudulent scheme, Relator adds new allegations that McKesson had a "top-down nationwide strategy" to offer the MA and RP in order to "induce customers to purchase drugs from McKesson," SAC ¶¶ 120–22, and that McKesson's sales force implemented this strategy, *id.* ¶¶ 129–33. Relator's new nationwide allegations solely and improperly rely upon information obtained in discovery. However, even with the benefit of discovery, Relator's allegations fail to meet Rule 9(b)'s particularity requirement.

LEGAL STANDARD

To survive a motion to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure, "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). A claim only has facial plausibility "when the plaintiff pleads factual content that allows the court to draw the *reasonable* inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556) (emphasis added). Under Rule 8, conclusory allegations and speculation "'will "not suffice to [defeat] a motion to dismiss."'" *United States ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 810 (S.D.N.Y. 2010) (quoting *Achtman v. Kirby, McInerney & Squire, LLP*, 464 F.3d 328, 337 (2d Cir. 2006)). Courts need not credit allegations that require an unreasonable inference or unwarranted deduction. *See Schorr v. Dopico*, 205 F. Supp. 3d 359, 363 (S.D.N.Y. 2016), *aff'd*, 686 F. App'x 34 (2d Cir. 2017).

FCA claims are also subject to the heightened pleading standard of Rule 9(b), which means that FCA complaints must "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). Where an FCA claim is predicated on a violation of the AKS, "both the

FCA and AKS violations must be pled in compliance with Rule 9(b)." ECF No. 155 at 12 (collecting cases). To satisfy this heightened pleading requirement, a complaint is required to "adduce specific facts supporting a strong inference of fraud." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 82 (2d Cir. 2017).

ARGUMENT

I. The SAC Must Be Dismissed Because it Does Not Sufficiently Allege a Knowing and Willful Violation of the AKS.

Relator's FCA claims are premised on alleged violations of the AKS. In order to plead an AKS violation, Relator must allege facts from which the Court can plausibly infer that McKesson acted "*knowingly and willfully.*" *See* 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). The scienter standard of the AKS is a rigorous one, which requires proof that a defendant acted with knowledge that its conduct was unlawful. *See* ECF No. 155 at 22–25 (collecting cases).

A. As Held By This Court, The AKS Scienter Standard Requires Relator to Plausibly Allege that McKesson Knew Providing MA and RP to Customers Was Unlawful.

As this Court has held: "[T]o satisfy the AKS' scienter requirement, [Relator] must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful." *Id.* at 28. Relator's allegations of scienter must be specific and non-conclusory. *Pervez*, 736 F. Supp. 2d at 810 (rejecting "speculation and conclusory allegations" of scienter); *see also Morana v. Park Hotels & Resorts, Inc.*, No. 20-CV-2797 (RA), 2021 WL 1164010, at *3 (S.D.N.Y. Mar. 26, 2021) ("[T]he Court only accepts as true 'factual' allegations that are 'non-conclusory.'") (citing *Pyskaty v. Wide World of Cars, LLC*, 856 F.3d 216, 225 (2d Cir. 2017)); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-CV-00668-SAG, 2021 WL 4133713, at *8 (D. Md. Sept. 10, 2021) (dismissing FCA complaint containing only conclusory allegations of scienter).

Relator's allegations must also not require unreasonable inferences or deductions. *See Schorr*, 205 F. Supp. 3d at 363.

The Court previously rejected several types of allegations that do not plausibly allege scienter under the AKS, namely (1) "[a]llegations that McKesson knew remuneration to induce purchases was prohibited in general," and (2) allegations "identifying a policy that plausibly violates the AKS and alleging that a defendant had a general awareness of the laws regulating the pharmaceutical industry. . . ." ECF No. 155 at 29. Instead, the Court explained Relator must plead "facts from which the Court can infer that Defendants knew the conduct was unlawful and proceeded with the business practice regardless." *Id.* at 30–31; *see also id.* at 28–31 (collecting cases); *Fitzer*, 2021 WL 4133713, at *7 ("The fact that Defendants were aware of the AKS and its requirements says nothing about whether they were acting with an unlawful intent . . . ."). The Court noted that previous cases have found that allegations such as notice from counsel that a program may be unlawful, cancellation of a program due to concerns over its lawfulness, or the provision of services without legitimate value as pretext to provide remuneration, are the type of allegations that could suffice to plausibly allege AKS scienter. ECF No. 155 at 29–30.

B. Relator's New Allegations Do Not Raise a "Reasonable Inference" that McKesson Knew that Providing MA and RP to Customers Was Unlawful.

Seven years after filing this action, and with the benefit of a year of discovery and the Court's guidance on how to plead scienter, *see* ECF No. 155 at 29–30, Relator still fails to allege non-conclusory facts from which the Court can make a reasonable inference that McKesson knew its conduct was unlawful, because such facts do not exist. The SAC therefore fails to plausibly allege an AKS violation, the required predicate for Relator's FCA claims.

1. Relator's New, Unsubstantiated Allegations of Conversations Between Relator and McKesson Employees Do Not Raise an Inference of Scienter.

For the first time in his third complaint, Relator adds new allegations about three conversations he purportedly had with McKesson employees, which supposedly indicate McKesson's scienter. These allegations, which are notably unsupported by any external source, fall far short of the standard articulated by the Court in its decision dismissing the FAC.

Relator first alleges that he sent an instant message to his supervisor, Bennett Holtzman, during a training presentation. According to Relator, his message informed Mr. Holtzman that "McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session," and Mr. Holtzman responded that Relator should "continue his sales work and not to worry about the compliance policies that prohibited the sales practices that Relator (and all of McKesson's sales personnel nationwide) had been instructed by McKesson executives to use." SAC ¶ 164.

Even if the Court accepts this new self-serving allegation as true, Relator still fails to actually identify facts from which the Court could draw a reasonable inference that *McKesson* knew its conduct was *unlawful*. Relator's alleged message to and response from Mr. Holtzman are too vague to draw an inference that Mr. Holtzman had any understanding of whether McKesson's use of the MA and RP violated any internal compliance policies, let alone the AKS. Crucially, Relator does not even allege that he told Mr. Holtzman that provision of the MA or RP was unlawful or that it violated the AKS. This new allegation is therefore even weaker than the one rejected by the district court in *Fitzer* as insufficient to allege scienter. *See Fitzer*, 2021 WL 4133713, at *7 (finding that "the fact that Relator told Allergan that he believed the physician locator *violated the AKS* . . . [does not] indicate[] that Allergan was acting with malintent")

(emphasis added); *see also Schorr*, 205 F. Supp. 3d at 363 (noting that a court "need not credit . . . allegations where they are wholly conclusory or rely on unreasonable inferences"). A self-serving conclusory statement by Relator to his manager that sales practices generally may violate a compliance policy does not support an inference that McKesson had any knowledge that the provision of the MA and RP was unlawful.

Relator's second and third new allegations of conversations—again, recalled for the first time seven years after his original complaint—are also insufficient to plausibly allege that McKesson acted with knowledge that its conduct was unlawful. *See* SAC ¶¶ 165–66. In SAC ¶ 165, Relator alleges that he was part of "several conversations" with other McKesson sales employees about how use of the MA and RP was "unethical" and "wrongful" because the tools supposedly encouraged customers to purchase "the highest margin drugs," which led to higher costs for patients and payors. *Id.*[2] And in SAC ¶ 166, Relator describes an alleged conversation with a McKesson employee about how it was "inappropriate" to provide the MA to Open Market customers because it had been "created originally" for customers of U.S. Oncology ("USON"), a separate division within McKesson. Relator's allegations about these purported conversations lack any details about their time, place, or circumstances, but even if a few McKesson sales employees thought that use of the MA and RP might negatively affect patient costs, or disagreed with McKesson's business strategy for the tools, that does not raise the inference that McKesson knew provision of the MA and RP to customers was *unlawful*. *See* ECF No. 155 at 28–29.

[2] Relator alleges in this paragraph that the highest margin drugs were almost always the highest priced drugs. This allegation is not supported even by the sample MA spreadsheet Relator attached to his SAC. In SAC Exhibit 3, a MA excerpt for 2012 Q4 for Summit Cancer Care, the highest margin drug was often the less expensive option. *See, e.g.*, ECF No. 159-3 at 3 (comparing ARANESP ($1626.32, with a profit of –$454.04) and PROCRIT ($1327.39, with a profit of $222.35)).

Moreover, these alleged conversations took place with Relator's fellow sales employees in the Southeast region, not anyone in a nationwide executive or management role. Even if knowledge of unlawfulness could even be attributed to these statements (which it cannot be), such knowledge cannot be imputed to McKesson. These allegations highlight that Relator has not, and indeed cannot, plausibly allege scienter.

2. Relator's Allegations that a McKesson Executive Forwarded Internal Business Analyses Does Not Raise a Reasonable Inference of Scienter.

Relator also attempts to allege scienter through reference to an email in which Kirk Kaminsky, then McKesson's Senior Vice President of Open Market Sales, forwarded multiple lengthy USON documents to Diana Verrilli, Senior Vice President of Payer Solutions, with the cover email "You didn't get this from me . . . ok?" SAC ¶ 160; *see also* Declaration of Nicholas Pastan ("Pastan Dec."), Exs. 1(a)–(d).[3] Relator asks the Court to infer from this brief, vague email that McKesson understood that provision of the MA and RP by its Open Market business unit—a different unit from USON, which is the subject of the documents—"was wrongful or unlawful." SAC ¶ 160. This allegation is particularly unreasonable, and should not be credited.[4]

[3] The Court may consider the documents referenced in the SAC at this stage because they are incorporated by reference. *See In re Cocoa Servs., LLC*, No. 17–11936–JLG, 2018 WL 1801240 (S.D.N.Y. Apr. 13, 2018) (quoting *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007) ("'The materials that may be considered on a motion to dismiss are those 'asserted within the four corners of the complaint . . . and any documents incorporated in the complaint by reference.'"). Further, even where a document has not been incorporated by reference, "the court may nevertheless consider it where the complaint 'relies heavily upon its terms and effect,' which renders the document 'integral' to the complaint." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (citation omitted).

[4] Relator's reliance on documents produced in discovery to attempt to allege scienter is also improper for the reasons articulated in Section II.A., *infra*. Nonetheless, the documents quoted in the SAC undermine an inference of scienter. For instance, at least one document referred to in the SAC shows that other companies openly offered similar tools, *see* SAC ¶ 141 (referring to Pastan Dec., Ex. 2, at 16) (showing another company offers a Regimen Analysis Tool), which undercuts an inference that McKesson knew its provision of these tools was unlawful. *See United States ex rel. Banigan v. Organon USA, Inc.*, No. CV 07-12153-RWZ, 2016 WL

See Schorr, 205 F. Supp. 3d at 363; *see also Fitzer*, 2021 WL 4133713, at *8 (finding that the relator failed to sufficiently allege facts supporting scienter under the AKS because he took "facts that are not necessarily indicative of the Defendants' willfulness, and then ask[ed] the Court to credit his conclusions that they are").

First, Mr. Kaminsky's email forwarded multiple eighty-plus page USON documents, in which the MA and RP programs were discussed only marginally. *See* Pastan Dec., Exs. 1(b), 1(c). The first attachment is an eighty-four page presentation to a single physician practice—Arizona Oncology—titled "Partner Value Proposition Project Results," which discusses the potential benefits of Arizona Oncology joining McKesson's USON network. Pastan Dec., Ex. 1(b). This document is irrelevant to Relator's claims, which extend only to McKesson's Open Market business unit. *See* SAC ¶ 50 ("Relator's allegations concerning the illegal inducements McKesson offers to physician practices pertain to the 'open market' division in which Relator worked as a BDE.").[5] Pastan Dec., Ex. 1(b). Even if it were relevant, the document contains only two brief mentions each of the MA and RP. *Id.* at 37, 53 (MA), 27, 32 (RP). The second attachment, "Value Services Provided by McKesson to US Oncology Network Practices," again

10704126, at *3 (D. Mass. Aug. 23, 2016) (evidence that practice was "an industry custom in which other pharmacies openly participated," was evidence that "favor[ed]" defendant's position that it did not have the requisite scienter under the AKS).

[5] In the FAC, Relator explicitly distinguished facts related to USON from those related to McKesson Specialty Health's ("MSH's") Open Market division. The FAC stated that Relator's allegations "pertain *only* to the 'open market' division." FAC ¶ 48 (emphasis added). In the SAC, Relator deleted "only" from this allegation and added an additional sentence, which attempts to justify his reliance on USON documents in the SAC: "However, USON's development, use, and valuation of the same business tools used by both USON and MSH reveals the value of those tools." SAC ¶ 50. This sentence, however, does not compel a different interpretation of the documents incorporated into SAC ¶ 160, which do not support a finding of scienter related to the Open Market division's use of the MA and RP.

pertains to USON and does not contain a single mention of the RP. Pastan Dec., Ex. 1(c). The third attached document, a one-page chart, mentions neither tool. Pastan Dec., Ex. 1(d).

Second, Mr. Kaminsky's email forwarding these *USON documents* in no way supports the inference that McKesson knew that the *Open Market's use* of the MA and RP programs was unlawful. *See* Pastan Dec., Ex. 1(a). Given the scarcity of information about the MA and RP in these documents, Mr. Kaminsky most likely forwarded them not even knowing that they contained *any* information about the tools. Furthermore, nowhere in the cover email is there any indication about why Mr. Kaminsky writes "You didn't get this from me . . . ." Pastan Dec., Ex. 1(a). There are no doubt a number of reasons why Mr. Kaminsky may have written that, none of which suggest that he or anyone else at McKesson believed that use of the MA or RP was unlawful. It is unreasonable to infer that this cover email evidences McKesson's knowledge that the specific programs at issue in the SAC, as used by the business division at issue in the SAC, were unlawful.[6] Finally, that this allegation serves as the cornerstone of Relator's "Additional Allegations of Scienter" only emphasizes his inability to plead scienter.

3. Relator's Spurious Allegations of Purported Document Destruction Do Not Raise a Reasonable Inference of Scienter, and Should be Stricken.

Relator also alleges that McKesson improperly destroyed documents because it knew its conduct with respect to the use of the MA and RP was wrongful. *See* SAC ¶¶ 167–70. Relator previously raised these exact spurious allegations before Judge Cott in multiple letter motions,

[6] SAC ¶ 160 also refers to a "task force" set up by Mr. Kaminsky, which Relator alleges "re-emphasized that the Margin Analyzer should be used as the centerpiece of McKesson's sales efforts." This characterization is unsupported, as demonstrated by the email referenced in this paragraph. *See* Pastan Dec., Ex. 3. In the email, Matt McClellan asks Diana Verrilli why the MA had been *removed* from the scope of FY15 projects, and Ms. Verrilli notes that Mr. Kaminsky had been asked to set up a task force on "our overall strategy in this area . . . [which would] consider some options, one of which will be embedding this functionality into CVP." *Id.* This email only supports an inference that the MA was *not* the centerpiece of McKesson's sales efforts, as it had been defunded as a FY15 project.

and was given a hearing on these allegations on January 12, 2022. On a full record, Judge Cott found that there was nothing to suggest that McKesson improperly destroyed documents, and that Relator's suggestion otherwise was pure speculation. *See* ECF No. 144, Hr'g Tr. (Jan. 12, 2022), at 7:19–8:23, 21:17–22:9; *see also id.* at 5:17–21 ("I don't think there is enough in the record, at least as has been described to me, to suggest that there was some improper destruction of these documents prior to the issuance of the CID which occurred after the phase one period."). Indeed, as Judge Cott pointed out, the complained-of document destruction "seems to have occurred in the normal course of McKesson's document destruction policies, which took place in advance of the CID being issued . . . ." *Id.* at 21:23–25. At the hearing before Judge Cott, Relator's counsel even admitted "we don't know what was destroyed and when." *Id.* at 9:5–6. Yet, Relator revives these baseless allegations attempting to manufacture scienter at this late stage. Relator's rank and rejected speculation does not raise a reasonable inference that McKesson improperly destroyed documents because it believed that its use of the MA and RP was unlawful.

Given the outrageous and unsupported nature of these allegations, McKesson respectfully requests that in addition to finding them insufficient to plausibly allege scienter, the Court strike the allegations of document destruction in SAC ¶¶ 167–70 under Rule 12(f) as scandalous and immaterial. *Oram v. Soulcycle, LLC*, 979 F. Supp. 2d 498, 512 (S.D.N.Y. 2013) (striking "unnecessary and inappropriate" allegations that were "prejudicial to Defendants"); *see also G-I Holdings, Inc. v. Baron & Budd*, 238 F. Supp. 2d 521, 555 (S.D.N.Y. 2002).

4. Relator's New Allegations that McKesson's Website No Longer Contains Much Information About the MA Fails to Plausibly Allege Scienter.

Finally, within its unsupported allegations that McKesson destroyed evidence, Relator also alleges that McKesson removed the MA from its website, which shows "knowledge of

guilt . . . ." SAC ¶ 167. This allegation is a transparent attempt to walk back allegations in the FAC that McKesson openly advertised the MA and RP, which this Court found undermined allegations of scienter. ECF No. 155 at 30 (explaining that allegations that McKesson openly advertised the MA and RP suggest that McKesson believed offering the tools was lawful). Relator's new allegation has no good faith reasonable basis and is contradicted by other allegations in the SAC, which make clear that the MA and RP were openly advertised during the relevant time period. *See, e.g.*, SAC ¶ 167 (new allegation describing McKesson as "aggressively promoting the use of the Margin Analyzer and Regimen Profiler"); *id.* ¶¶ 72, 117, 130 (SAC allegations retained from FAC that the tools were openly advertised). That McKesson's website may contain different information about the MA today than during the relevant time period seven years ago does not plausibly support the inference that McKesson knew its conduct was unlawful. *See Iqbal*, 556 U.S. at 678 ("Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" (citing *Twombly*, 550 U.S. at 557).). Furthermore, the SAC contains no allegation that McKesson removed the RP from its website, and by all accounts RP is still openly advertised. This new allegation thus does not plausibly allege scienter with respect to the MA during the relevant time period and is irrelevant to scienter as to the RP.

C. Relator's Remaining Additional Allegations of Scienter Merely Repeat Claims Already Rejected by the Court as Insufficient to Allege Scienter.

Beyond the new types of allegations contained in the two sections of the SAC detailed above, Relator has added other new allegations to those sections and throughout the SAC. These allegations simply repeat and build upon the types of allegations the Court previously rejected.

Many of Relator's additional allegations fail to state a claim because they are conclusory. *Pervez*, 736 F. Supp. 2d at 810; *Fitzer*, 2021 WL 4133713, at *8 ("Relator may not simply

conclude that Defendants acted with an unlawful purpose; he must allege specific facts that support an inference that Defendants were, in reality, acting with that purpose."). The Court dismissed the FAC because it "lack[ed] any [] non-conclusory allegations as to scienter," and the SAC is no different. ECF No. 155 at 31. In SAC ¶¶ 8, 156, 159, 162, and 163, Relator puts forth legal conclusions that mimic the scienter standard rather than specific facts suggesting that McKesson knew its conduct was unlawful. For example, SAC ¶ 162 alleges:

> "All of the foregoing individuals further knew that the Regimen Profiler and the Margin Analyzer were separate and apart from, and not an integral part of, the drugs that McKesson sold to practices . . . . Thus, these executives and employees knew that it was wrongful and unlawful to offer those tools for free to physician practices as a quid pro quo to secure purchase commitments."

Such allegations, which make conclusory statements about the knowledge of individuals without tying the alleged knowledge to plausible facts, cannot save the SAC.

The SAC also contains more allegations like those that doomed the FAC: (1) McKesson provided extensive compliance training, (2) McKesson knew that the MA and RP had value, and (3) McKesson used the MA and RP "to induce customers to purchase drugs from McKesson." *See*, *e.g.*, SAC ¶ 159; *see also* SAC ¶¶ 8, 157–58. Not only are these allegations conclusory and unsupported by specific facts, *see Fitzer*, 2021 WL 4133713, at *8, they are also insufficient because they are just like allegations previously rejected by the Court. This Court already held that allegations in the FAC that McKesson was "aware[] of the requirements of the AKS and the general unlawfulness of inducements," *see* FAC ¶¶ 111–12, that the MA and RP constitute remuneration under the AKS, *see id.* ¶¶ 102–10, and that the MA and RP were used to induce purchase commitments, *see id.* ¶ 71, do not state a claim because they cannot "support a finding

that McKesson knew this particular course of conduct was unlawful." ECF No. 155 at 29. The new allegations in Relator's SAC fail for the same reason.[7]

II. The SAC's Claim that McKesson Engaged in a Nationwide Fraudulent Scheme Fails Rule 9(b)'s Particularity Requirement and Relies Improperly on Discovery.

The SAC should also be dismissed pursuant to Rule 9(b), because Relator fails to allege facts that support a "strong inference" that McKesson engaged in the purported nationwide fraudulent scheme. *See Chorches*, 865 F.3d at 82. In the Court's decision dismissing Relator's FAC, the Court declined to rule on the sufficiency of Relator's allegations that McKesson engaged in a nationwide fraudulent scheme involving the MA and RP in part because Relator represented that he could provide additional information regarding nationwide scope in his SAC. *See* ECF No. 155 at 33–34 (citing Mar. 8, 2022 Oral Argument Tr. at 25–26). The SAC's new allegations about McKesson's purported nationwide conduct are not based on Relator's personal knowledge. Again, Relator improperly relies on unreasonable accounts of documents produced during the year of discovery that preceded the FAC's dismissal. Whether or not the Court considers these documents, the SAC fails to satisfy Rule 9(b)'s particularity requirement.

A. The SAC Improperly Relies on Documents Produced in Discovery.

At the motion to dismiss hearing, Relator represented to the Court that he could supplement his allegations that McKesson engaged in a nationwide scheme in a manner that would cure the deficiencies in his complaint, including to meet the requirements of Rule 9(b). *See* ECF No. 153, Mar. 7, 2022 Oral Argument Tr. at 25–26. However, Relator did not

[7] Further, Relator's additional allegations rely on documents that show that the MA and RP were among a variety of "value add" tools that could be provided to physicians, highlighting that McKesson viewed the value add tools as a set, rather than independently. *See, e.g.*, Pastan Dec., Ex. 4 (document cited in ¶ 121, listing MA and RP as two of nearly two-dozen items listed under McKesson Specialty Health "Products, Programs, and Services"). This undercuts any inference that McKesson employees knew that providing those tools (but not others) violated the AKS.

supplement his allegations with information about which he has personal knowledge. Instead, in the SAC, he attempts to satisfy Rule 9(b) with allegations consisting of pieced-together quotes from a few of thousands of documents produced during discovery. Rule 9(b) is meant to act as a gatekeeper against Relator's attempts to access and use discovery without the adequate foundation in his own pleading. *See United States ex rel. Bingham v. HCA, Inc.*, No. 13-23671, 2016 WL 6027115, at *4–5 (S.D. Fla. Oct. 14, 2016) (dismissing relator's second amended complaint because without the benefit of cited discovery materials, the SAC would, "suffer[] from the same infirmities" as the FAC); *cf. Wood v. Applied Research Assocs.*, 328 F. App'x 744, 747 (2d Cir. 2009) ("A relator's contention, that discovery will unearth information tending to prove his contention of fraud, is precisely what Rule 9(b) attempts to discourage."). Because Relator's reliance on discovery to attempt to meet 9(b)'s pleading standard frustrates Rule 9(b)'s purpose, his allegations based on McKesson's documents should be disregarded for the purpose of assessing the sufficiency of his claims.

Relator should also be prohibited from relying on discovery to attempt to establish his nationwide FCA claims because it undermines the FCA's requirement that a relator have personal, non-public knowledge of the facts underlying his claims. *See* 31 U.S.C. § 3730(e)(4) (requiring an FCA relator to be an "original source" of the information underlying the action); *see also Bingham*, 2016 WL 6027115, at *4 (the FCA requires that relators have "independently-obtained knowledge of fraud" and that "[i]t is well settled that a *qui tam* relator may not present general allegations in lieu of the details of actual false claims in the hope that such details will emerge through subsequent discovery.") (citation omitted). Relator's allegations rely on decontextualized excerpts from documents about which he has no personal knowledge and unreasonably interprets. *See supra* at 11–13; *infra* at 19–21. Relator does not know the context

or purpose of the documents he references, nor does he know if certain resources or sales messages discussed were ever used with customers. These deficiencies serve to highlight why the FCA has a personal knowledge requirement and why, absent personal knowledge, the allegations cannot possibly satisfy Rule 9(b)'s requirements. The Court should therefore disregard Relator's new allegations and the documents upon which they rely.

B. The Additional Allegations in Relator's SAC Fail Under Rule 9(b) to Plead a Nationwide Fraudulent Scheme.

Though improper, the SAC's new allegations of McKesson's nationwide conduct still fail under Rule 9(b), which requires Relator to "adduce specific facts supporting a strong inference of fraud." *Chorches*, 865 F.3d at 82. Where an FCA claim is predicated on a violation of the AKS, both the FCA and AKS violations must be pled in compliance with Rule 9(b). ECF No. 155 at 12 (collecting cases). Relator therefore must "plead with particularity the who, what, when, where and how of the fraudulent . . . scheme." *United States ex rel. Mooney v. Americare, Inc.*, No. 06–CV–1806, 2013 WL 1346022, at *4 (E.D.N.Y. Apr. 3, 2013) (internal quotation marks omitted). The SAC's new vague and conclusory allegations that McKesson had a "top-down nationwide strategy" to use the MA and RP to induce purchase commitments, *see, e.g.*, SAC ¶¶ 120–22, 129, and the SAC's new appendices listing additional physician practices that purportedly received the tools, fail to meet this burden.

1. The SAC's Vague Allegations Regarding a Fraudulent "Top-Down" Corporate Strategy Do Not Satisfy Rule 9(b).

Relator's general and implausible allegations that McKesson had a "top-down nationwide strategy" involving the provision of the MA and RP fail to satisfy Rule 9(b). These allegations rely on misleading excerpts of lengthy documents, require the Court to make unreasonable inferences about McKesson's conduct, and fail to provide the types of specific details other courts have found necessary. Relator's allegations based on discovery documents thus do not

support a *reasonable inference* that McKesson engaged in a nationwide fraudulent scheme. *See Schorr*, 205 F. Supp. 3d at 363 (noting that allegations that are "wholly conclusory or rely on unreasonable inferences and unwarranted deductions" need not be credited by the court). A close look at the allegations in SAC ¶¶ 121(a)–(c), which contain the primary support for the SAC's section titled "McKesson Adopted a Top-Down Corporate Strategy to Use the Margin Analyzer to Induce Purchase Commitments and to Avoid Competition on the Basis of Drug Pricing," reveals how Relator's new allegations based on discovery material fail:

- In SAC ¶ 121(a), Relator cites a 2011 presentation that Relator alleges was "given to a group of McKesson executives," which purportedly identifies Onmark Select (not the MA or RP) as a priority area and urges McKesson executives to "start selling on value" rather than price. Relator alleges that the document describes the MA as a "value driver." SAC ¶ 121(a). As an initial matter, the presentation slide Relator appears to reference does not include the MA or RP on the list of McKesson's "value drivers." *See* Pastan Dec., Ex. 5, at 28. Further, simply urging executives to sell on "value" does not indicate a strategy to engage in fraudulent activity using the MA and RP. Finally, this factual allegation does not contain any information about whether McKesson actually adopted the approach discussed, who it was used with, how it was used, or when it was used.

- In SAC ¶ 121(b), Relator cites a December 2012 email thread in which Tesh Khullar says that after a competitor settles into the marketplace, McKesson would "understand what the incremental price clinics are willing to pay for our value add services." SAC ¶ 121(b); Pastan Dec., Ex. 6, at 1. Relator alleges that this email indicates a nationwide strategy to induce purchases from McKesson using the MA and RP. Relator omits, however, that the MA and RP are not mentioned in this document. This document cannot support an inference that McKesson violated the AKS and FCA by providing the MA and RP to customers.

- In SAC ¶ 121(c), Relator cites a document he calls, "RFP Response Toolkit" to support the allegation that McKesson highlighted the MA and RP as tools for its customers. However, the "RFP Response Toolkit" does not focus on the MA or RP. The nine-page document is a specific overview of McKesson's customer resources, and only one paragraph is dedicated to each of MA and RP. Pastan Dec., Ex. 4, at 5. The document otherwise focuses on other McKesson products, programs, and services. The SAC also contains no allegations as to whether, how, when, or by whom this Toolkit was used.

The allegations in SAC Paragraphs 121(a)–(c) are only a few of the many instances where Relator's allegations based on discovery materials are either unsupported by the

documents Relator cites, or fail to adequately allege sufficient detail of the purported nationwide scheme. For example, Relator provides insufficient details about what messages about the MA and RP were actually delivered to specific nationwide customers, who delivered the messages, or how or whether specific customers actually used the tools. Quoting internal deliberations about a *potential* marketing strategy from executive-level employees fails to meet this requirement, as it does not identify which McKesson employees actually delivered allegedly unlawful marketing messages to customers or what those McKesson employees actually told customers. *See United States ex rel. Worsfold v. Pfizer, Inc.*, No. 09-11522, 2013 WL 6195790, at *9 (D. Mass. Nov. 22, 2013) (dismissing relator's complaint alleging a fraudulent scheme to promote off-label drug use where the relator failed to allege any "statements made by specific employees of [defendant] to any physicians in order to promote the off-label uses . . . .").

Although Relator may argue that he does identify specific statements by McKesson sales employees, such as in SAC ¶ 129, the statements referenced in this paragraph only generally discuss McKesson's "value added" services and do not raise specific allegations regarding MA or RP. *See infra* n.7. These limited statements, taken from discovery materials, do not support a reasonable inference that McKesson used the MA or RP to promote a fraudulent scheme and do not suffice to allege that these statements were communicated nationwide. *See Schorr*, 205 F. Supp. 3d at 363. The SAC's new allegations about nationwide training and sales practices related to the MA and RP, *see* SAC ¶ 126, are also based on a sales training document about "value-added services" in general—again offering a dubious interpretation of McKesson's documents, *see also* SAC ¶ 122 (discussing "value-added services" generally); SAC ¶ 131 (discussing how "value-added services" allegedly "induced" customers).

Relator's vague and general allegations are similar to those that other courts have deemed insufficient to plausibly allege nationwide FCA claims. *See, e.g.*, *United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 730–31 (N.D. Ill. 2020). The relator in *Suarez* alleged that the defendant had created a nationwide fraudulent marketing strategy "'designed to offer a sweeping geographic reach,'" and that employees from across the country attended sales meetings regarding the strategy in order to use it with customers nationwide. *Id.* at 721. The *Suarez* court rejected these allegations as "too vague" to support an inference of nationwide fraud. *Id.* at 730. The SAC's allegations about a general sales strategy involving the MA and RP based on a "top-down" strategy fail for the same reason.

The SAC's appendices, which list 113 practices throughout the country that Relator alleges "submitted claims for reimbursement to government health agencies after being offered the Margin Analyzer (or Regimen Profiler) as a kickback," SAC ¶ 56, ; *see also* SAC Appendices 1, 2, are insufficient to expand Relator's claims nationwide. Simply listing practices does not provide the specific information Rule 9(b) requires, and leaves wholly unclear how the MA or RP were allegedly used by McKesson as a kickback, or with the physician practices as part of a nationwide fraud. *See Conte v. Kingston NH Operations, LLC*, No. 1:20-CV-0647 (GTS/CFH), 2022 WL 356753, at *14 (N.D.N.Y. Feb 7, 2022); *see also United States ex rel. Doe v. Lincare Holdings, Inc.*, No. 5:15-CV-19-DCB-MTP, 2017 WL 752288, at *6 (S.D. Miss. Feb. 27, 2017) (dismissing FCA action as "lack[ing] the requisite indicia of the specific scheme to submit false claims" where the complaint "fails to identify any [] personnel who [participated in the scheme] or any [] personnel who submitted false claims as a result").

Finally, the SAC also does not adequately explain how McKesson's provision of the MA and RP to any of the newly identified customers resulted in the submission of a false claim to the

government (i.e., how the allegedly false claims "result[ed] from" the alleged AKS violation). *See* 42 U.S.C. § 1320a-7b(g). Relator alleges only that McKesson provided the MA "on a quarterly basis," and therefore suggests that the false claims are "Medicare reimbursement claim[s] submitted by a physician practice *in the quarter following* McKesson's offer of [the MA] or the practice's receipt of [the MA] . . . ." SAC ¶¶ 55, 57 (emphasis added). This allegation fails to explain how any of the customers that were allegedly provided the MA and RP actually used the tools or made purchasing decisions based on them. Relator's threadbare allegation that some undetermined number of practices must have purchased medicines from McKesson, and some undetermined number of physicians must have prescribed them to patients, only because McKesson provided them the MA and RP tools, is insufficient to satisfy Rule 9(b).[8] *Lawton ex rel. United States v. Takeda Pharm. Co.*, 842 F.3d 125, 131–32 (1st Cir. 2016) ("ask[ing] [the court] to infer that a portion of these funds must have been used to pay unlawful claims . . . falls short of Rule 9(b)'s requirements") (citation omitted); *see also United States ex rel. Chapman v. Off. of Children's & Fam. Servs.*, No. 04-1505, 2010 WL 610730, at *4 (N.D.N.Y. Feb. 16, 2010) (dismissing complaint under Rule 9(b), and noting that the relator "'summarily conclude[d] that the defendants submitted false claims to the government'"). Furthermore, Relator's allegation fails to adequately plead damages for the purported nationwide

[8] While this Court previously ruled that Rule 9(b) only requires Relator to provide allegations supporting a "strong inference" that the complaint practices actually submitted claims for reimbursement to federal health care programs, ECF No. 155 at 32, currently before the United States Supreme Court are three petitions for certiorari that may clarify this standard. In two of these cases, the Sixth and Eleventh Circuits held that a relator's pleading fails under Rule 9(b) unless the relator identifies specific claims that were submitted pursuant to a fraudulent scheme. *United States ex rel. Owsley v. Fazzi Assocs., Inc.*, No. 19-4240 (6th Cir. Oct. 13, 2021), *petition for cert. filed*, 2021 WL 6118289 (Dec. 21, 2021); *Est. of Helmly v. Bethany Hospice and Palliative Care of Coastal Ga., LLC*, 853 F. App'x 496 (11th Cir. 2021), *petition for cert. filed*, 2021 WL 4441324 (Sept. 23, 2021). *But see United States ex rel. Prose v. Molina Healthcare of Ill., Inc.*, 17 F.4th 732, 741 (7th Cir. 2021), *petition for cert. filed*, No. 21-1145 (Feb. 14, 2022).

fraud, because from the SAC one cannot plausibly infer that customers actually received MAs or RPs quarterly, or ever used the MA or RP, much less that any use of an MA or RP resulted in the submission of false claims or damages.

2. The SAC Does Not Adequately Allege When the Purported FCA Violations Occurred.

Relator alleges that Defendants' FCA violations continue to the present. *See* SAC Counts I–XXIX (Defendants "have damaged and continue to damage" the United States and 29 states and the District of Columbia under the False Claims Act and state analogs). However, he makes no specific allegations regarding the purported FCA violations after 2015. The Court should therefore dismiss all claims after 2015 for failure to satisfy Rule 9(b).

Under Rule 9(b), Relator's SAC must specify the time period during which the allegedly false claims were filed. *See United States ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 132 (E.D.N.Y. 2018) (dismissing qui tam relator's claim where relator failed to "allege dates, or even an approximate range of dates, on which [defendant] filed false claims"); *United States v. Comstor Corp.*, 308 F. Supp. 3d 56, 78, 92 (D.D.C. 2018) (dismissing relator's claim where, though relator alleged a 13-year period of conduct, the complaint only provided specific allegations of conduct between 2008 and 2013, noting that "specific examples should cover the relevant time period"); *see also United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:11-CV-962-WSD, 2013 WL 2303768, at *7 (N.D. Ga. May 17, 2013). However, the SAC contains no specific allegations regarding use of the MA later than 2015, or the RP later than 2013. The SAC instead contains only the conclusory and general allegation that McKesson sales representatives offered the MA to customers "[f]rom 2011 until at least 2019,"—five years after Relator terminated employment with McKesson—and that "between 2012 and November 30, 2017" McKesson customers who received the MA and RP submitted claims for reimbursement

to Medicare. *See* SAC ¶¶ 54, 153. Relator may point to the SAC's Appendices to attempt to establish a broader date range, but these are insufficient. SAC Appendix 1 merely alleges that some customers may have received an MA as late as a *single* quarter in 2016 or 2017, and SAC Appendix 2 includes no allegation that any customer received the RP after 2013. Relator's threadbare and conclusory allegations about the post-2015 time period are insufficient to maintain a nationwide FCA case to the present under Rule 9(b). *See Piacentile*, 336 F. Supp. at 132 (noting that a relator's allegations "might support, at most, allegations that [defendant] filed false claims in the early part of the last decade" where the complaint had no specific allegations later than that time). At a minimum, all claims for post-2015 conduct should be dismissed.

Because Relator fails to plead fraud with particularity, Relator's nationwide FCA claims should be dismissed. Alternatively, the Court should narrow Relator's claims to only the geographic area and time period for which it finds Relator has pled fraud with particularity. *See Suarez*, 503 F. Supp. 3d at 730 (limiting FCA case to claims in a single jurisdiction because the relator's complaint offered only vague allegations supporting an alleged nationwide scheme).

CONCLUSION

Relator has had seven years and three chances to plead his case. For the foregoing reasons, the Court should dismiss the SAC with prejudice and without further leave to amend.

Respectfully submitted,

/s/ Ethan M. Posner
Ethan M. Posner
Krysten Rosen Moller
Nicholas O. Pastan
COVINGTON & BURLING LLP
850 Tenth Street, NW
Washington, DC 20001
eposner@cov.com
krosenmoller@cov.com
npastan@cov.com

Thomas E. Garten
COVINGTON & BURLING LLP
3000 El Camino Real
5 Palo Alto Square
Palo Alto, CA 94306
tgarten@cov.com

Counsel for Defendants